Day of Dialogue

Insights and Evidence from Product Introduction: Lessons for Microbicides

by Martha Brady and Elizabeth McGrory

Report of a meeting
12 March 2007

Population Council

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The Population Council conducts research worldwide to improve policies, programs, and products in three areas: HIV and AIDS; poverty, gender, and youth; and reproductive health.

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http://www.popcouncil.org/pdfs/DoDMicrobicides.pdf

Acknowledgments

The Day of Dialogue was intended to stimulate discussion and to share insights and evidence from a broad range of product introduction efforts. The meeting drew upon the collective experience and wisdom of many people. We wish to thank the meeting presenters for their high-caliber presentations and all meeting participants for their contribution to an engaging and productive discussion. We are especially grateful to Jeff Spieler for his valuable contribution to the overall conceptualization of the meeting and for his unwavering support throughout.

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A successful microbicide would be a product—likely delivered in a gel, foam, ring, or cream—that would reduce the transmission of HIV and, possibly, other sexually transmitted infections when used during intercourse. A number of candidate products are being developed,[1] and several are expected to complete safety and efficacy trials in the near future. Researchers and program planners are considering how an effective microbicide can be made available to the women who need it most. Microbicide introduction efforts will need to be carried out within a range of local social contexts and service environments, and will have to consider the various cultural practices surrounding marriage, sexual violence and coercion, and women's economic dependence on men that leave many women vulnerable to HIV and AIDS.

Because microbicides are a new product category, no clear model exists for how best to introduce and integrate microbicides into developing-country health systems. However, experience with introducing contraceptives and other health care technologies provides evidence and insights that can inform microbicide introduction. Drawing on its leadership in the microbicide field and its long history of work in product development and introduction, the Population Council convened a day-long meeting of experts to review product introduction experiences and identify key features that can guide microbicide introduction. This Day of Dialogue brought together 45 leaders from two dozen nongovernmental, governmental, advocacy, and donor organizations. Speakers and participants have backgrounds in product introduction and social marketing, clinical trials and product development, and reproductive health and HIV/AIDS and have extensive experience in designing and implementing introduction programs in developing countries.[2]

The meeting was designed to highlight lessons from a range of technology intro-

Presentation topics included

- Building a platform for women's HIV prevention
- Update on the microbicides pipeline
- Emergency contraception: Use dynamics and messaging
- Challenges and opportunities related to the female condom
- Introducing a package of products: Cyclebeads, condoms, and EC
- Commercialization of products for "taboo" health areas: An industry perspective
- Social marketing of health products that require new behavior: A look at bednets and point-of-use water treatment
- A process of innovation: History of contraceptive implants (Norplant®)
- Emerging tools in HIV prevention: Male circumcision
- Lessons for microbicides: Facilitated discussion

[1] For an overview of microbicide product development see www.microbicide.org.

[2] A listing of presentations and participants appears on pages 11–16 of this report.

duction experiences: emergency contraception, the female condom, the standard days method (SDM) of fertility awareness,[3] insecticide-treated bednets, point-of-use water treatment, and Norplant®. These are examples of prevention products (to prevent either pregnancy or disease) that require information and support to be used effectively and have varying levels of effectiveness. Because first-generation candidate microbicides are also user-controlled, involve sex and sexual practices, and challenge gender norms, lessons from existing products that share similar features—including emergency contraception and the female condom—are relevant. Other speakers reviewed private-sector approaches to introducing "taboo" health products, and the status of male circumcision for preventing HIV infection.

This report outlines some of the key lessons and findings that emerged under several broad themes: increasing HIV protection; putting effectiveness into perspective; disentangling need, demand, and use; bridging clinical trials and health system integration; considering population-level versus individual-level risk and benefits; and product positioning and marketing strategies. All of these have implications for clients, providers, health delivery systems, and policy decisionmaking. While these cases and practical experiences should inform microbicide introduction, this critically important effort will need to combine both science—derived from evidence and experience—and art—drawing on creative and innovative thinking.

Increasing HIV protection by expanding options

Microbicides need to be introduced as part of a broad public health goal of increasing overall levels of protection and offering women more options for protection.

This will necessitate exploring how people make tradeoffs among different methods based on availability, perceived effectiveness, price, ease of use, and other factors. Lessons related to contraceptive use suggest that offering more options makes it more likely that women and couples can adopt a method that fits their needs. When considering introducing the standard days method (SDM), policymakers and providers were concerned that women would "switch" from other methods of contraception to the less effective SDM. However, research suggests that SDM attracted new contraceptive users, many of whom objected to other methods of contraception for different reasons: side effects, finding them difficult to use, perceived as being "unnatural," or on religious grounds. Similarly, incorporating female condoms into the method mix can increase the number of sex acts protected by both male and female condoms.

One approach to preparing for microbicide introduction is to build a "platform" for girls' and women's protection strategies by situating the introduction of women's

[3] The Standard Days Method (SDM) is a family planning method that standardizes fertility awareness. It is used with cyclebeads, which are a color-coded string of beads that help a woman track her cycle days, know when she is fertile, and monitor her cycle length. The SDM identifies days 8–19 of the cycle as fertile, and helps couples avoid unplanned pregnancy by knowing on which days they should not have unprotected sex, and can also help couples plan pregnancy by knowing on which days the woman is fertile.

HIV prevention products within a broader protection framework. Such an approach would focus on issues of equity and access to HIV prevention products and services; would include actions to redress gender-related power imbalances within societies, households, and intimate partnerships; and would make a concerted effort to enhance women's economic opportunities. This approach also requires breaking through the bottlenecks that have hampered the introduction of female-initiated products by investing in training, communication, and outreach, and by expanding the concept of service delivery to include a new set of actors, mechanisms, settings, and types of providers.

Experience with a range of health products has demonstrated the feasibility and acceptability of providing them outside clinic settings with little negative impact on quality. Research comparing clinic and community-based provision of SDM found no meaningful difference between the competency of these different provider types. This finding demonstrates that even a technology with extensive counseling and information requirements can be provided appropriately outside a formal clinic setting. At the same time, emergency contraception has increasingly been made available without a prescription; while this improves access it can compromise the quality of information and women's understanding of the product, unless efforts are made to ensure adequate provision of information. Such approaches are important to increase access to new prevention technologies in settings that are comfortable and convenient for different users. Striking a balance between relying on a wide range of distribution channels and maintaining the ability to monitor and evaluate patterns and dynamics of use is essential, particularly in early stages of product introduction. It is also essential to strengthen and retool existing HIV prevention programs to lay the foundation for microbicides and other new prevention technologies.

Female-initiated, coitally dependent methods require

Addressing provider bias up front

A long-term perspective and commitment:

- acceptability changes over time
- individual users have a learning curve and become more comfortable with the product over time

Incorporating concepts of sex, sexuality, and communication and negotiation skills into counseling and information provision

Challenging assumptions about sex and sexuality

Realistic expectations: "consistent" use is optimal but difficult to achieve

Sustained political and financial support to programs

Putting effectiveness into perspective

The microbicide field will continue to grapple with issues surrounding product efficacy and use effectiveness as it considers product introduction. Policymakers, providers, and activists sometimes express concerns about introducing a partially effective product like a microbicide for HIV prevention. How efficacious a microbicide must be, however, is shaped by the al-

ternatives. In the contraceptive field a 40–60 percent efficacious product would likely not be viable when compared with other contraceptive products with much higher efficacy—sometimes greater than 90 percent. But HIV prevention is very different. There are few effective options, and those that do exist—male and female condoms—are not widely available or used. In this context a partially effective product that is used consistently could offer an important protection strategy at both the population and individual levels.

People may be willing to tolerate different levels of imperfection (in a technology and in use of the technology) depending on their assessment of their own risk factors and the benefit the product may confer. For example, women and couples using SDM perceived it as a very effective contraceptive method because they were comparing it to the method they were currently using—nothing—rather than to highly efficacious methods like the IUD or pill that they were unable or unwilling to use. Microbicides will need to be introduced in the context of the range of prevention options such as male and female condoms, and women will need to understand the different levels of protection that each option affords. While it is unclear how individuals will balance considerations of effectiveness, ease of use, price, convenience, and pleasure, it is critical to ensure that women are provided with accurate and meaningful information about a product's effectiveness so that they can make their own assessments of different prevention options. The microbicide field could begin to develop and test communication and counseling strategies, information materials, provider training curricula, and policy initiatives to address the concepts and messages surrounding partial efficacy.

Disentangling need, demand, and use

The relationships between need, demand, and use of new products are complex and non-linear. Epidemiological data underscore the devastating impact of the AIDS epidemic and new HIV infections on women, who have few options under their control for preventing infection. Market research and acceptability studies show that women in various settings and circumstances express a high level of interest in microbicides. It is not clear, however, how these high levels of need and interest will translate into demand for a particular product once it is available. This uncertainty is even more pronounced for a product like a microbicide that is a "public health good" for which demand will need to be created, measured, and sustained among providers, policymakers, donors, and users. Provider and policymaker bias against the female condom interacted with the product's limitations, relatively high price, and need to provide information and support, with the result that widespread availability and use were curtailed.

Because microbicides are a new product category, demand for them will have to be created. Social marketing can play an important role in creating demand for microbicides by using mass media and other marketing approaches to increase understanding of disease transmission and how microbicides work, and to instill a belief in the benefits of the product. Such efforts have been used successfully for a variety of other products, including insecticide-treated bednets to prevent malaria and point-of-use water treatment to prevent diarrheal disease.

Acceptance and use of the "first-to-market" microbicide will set the stage—in both positive and negative ways—for future products. Therefore it is critical that initial introduction efforts are well conceived, well supported, and successful. Experience from other products suggests that it takes time to establish both a market and a reliable system to deliver the product—as illustrated by virtually all of the examples explored at the Day of Dialogue. Even with a product that is urgently needed, adoption is likely to be characterized by fits and starts. Donors and other key opinion leaders must be realistic about the time trajectory needed for widespread product adoption.

Population and individual impact

Public health advocates have long relied on modeling to estimate the population-level impact of new prevention technologies in order to build the case for investing in development and delivery of these products. As evidenced by several examples, however, it can be very difficult to demonstrate this kind of population-level impact, especially in the near term. Attempting to do so can create unrealistic expectations about the timing and rate of introduction, acceptance, and use of new prevention technologies. Demonstrating population-level impact in the early years of product adoption is not likely to be feasible for several reasons. First, almost all new products require time and substantial investment in order to be made widely available and used consistently. Second, measuring the public health impact of a new technology can be difficult—it requires a large amount of data collected over a long period of time, and it can be very difficult to tease out the impact of the technology itself from other interventions or broader societal changes. Typically, population-level impact of a prevention strategy is only visible after a long period—often decades.

Measuring impact has been a challenge for many products. For example, both insecticide-treated bednets and point-of-use water treatment have achieved increased sales in a number of settings where concerted investment has been made in social marketing programs. While a number of studies have shown that use of these products has increased along with sales, it has been difficult to measure impact on decreases in malaria or diarrheal disease. In seeking to expand access to emergency contraception (EC), a number of public health researchers and advocates maintained that doing so would lead to a decrease in unintended pregnancy and induced abortion, and they developed models to estimate the likely impact in different settings. While information about, access to, and use of EC have increased dramatically, recent research has been unable to demonstrate that EC has had a population-level impact on rates of unintended pregnancies and/or induced abortion.

The microbicide field should learn from these experiences. Researchers, public health officials, and advocates should be careful about basing an argument for product introduction solely on the expectation of a measurable impact on reducing HIV infection in women within a short timeframe. While having an impact on the AIDS epidemic is clearly the intention of those working on microbicides, making the case

for microbicide introduction should also be based on the human rights goal of providing more options for individuals—especially women—to reduce their risk of infection. This approach, coupled with careful monitoring and research, can help make the case for microbicides—and other new HIV prevention options—based on their benefits for both individuals and the population overall.

Bridging clinical trials and health system integration: Pre-introduction studies

After completing clinical trials, and during the time that regulatory files are being prepared and reviewed, researchers and service providers can continue to explore operational questions concerning product delivery that will not be addressed in a clinical trial. For example, social science and operations research can explore the feasibility and acceptability of various approaches to service delivery, training, and supervision for different types of providers. Research can also explore issues related to logistics and supply systems, patterns of use, and provision of information to users.

The experience with Norplant® implants provides an example of this pre-introduction phase as a bridge between clinical trials and widespread introduction through incorporation into national programs. The pre-introduction phase was pioneered by the Population Council in the 1980s to move products from clinical trials into national programs while ensuring attention to quality of care. This approach provides an opportunity to carefully and systematically introduce a product under more routine service conditions while continuing to closely monitor, control, and study the process. As described above, data and experience are generated on aspects of the product that are not studied in clinical trials, such as operational issues about product delivery, integration into health systems, and longer-term behavioral dimensions of product use.

Examples from Norplant and emergency contraception presented at the meeting underscored the importance of carefully planning the scope and setting for pre-introduction studies. In each case, an international consortium worked on various aspects of

Benefits of a pre-introduction phase

A pre-introduction phase offers an opportunity to address issues that can inform and improve product introduction. A well-designed and monitored pre-introduction phase:

- Serves as a bridge between the clinical trial and widespread incorporation into national programs
- Allows providers and health systems to gain experience with the product under routine service conditions
- Provides critical training to medical opinion leaders
- Allows for monitoring and gathering data on practical aspects of service delivery that are not routinely collected in trials
- Builds partnerships between technical agencies with unique capacities (e.g. service delivery; information, education, and communication; monitoring and evaluation)
- Offers opportunities for expanded community engagement and policy dialogue to establish a good foundation for product introduction

Product introduction frameworks

Many product introduction efforts have developed frameworks that outline critical elements of the process. These frameworks use different terminologies and generally reflect the unique characteristics of the product being considered, be it emergency contraception, Norplant, or the female condom. Nevertheless, most of them share a number of common elements:

- Assess users' needs and perspectives
- Create a communication strategy
- Determine service capacity and ability to deliver
- Build policy, financial, and provider support
- Obtain registration and regulatory approval
- Ensure supply of product through financing and procurement mechanisms
- Develop distribution plans
- Conduct provider training
- Conduct ongoing monitoring and evaluation
- Develop, implement, and adapt programs for user education and support

The microbicide field can build on and adapt these elements to develop a microbicide-specific introduction strategy.

product availability and delivery, including planning the pre-introduction and other operations research efforts. Both consortia used a consultative process to determine the key questions to be addressed in these studies, and to develop the appropriate protocols to examine those questions. The Emergency Contraception Consortium developed different approaches that were tested in four countries. Pre-introduction studies for both Norplant and EC were conducted in settings where the products were new, as well as in settings where trials had been conducted. (In contrast to the case of microbicides, EC and Norplant trials were conducted and initial regulatory approvals were granted in developed countries.) Lessons from EC and Norplant underscore the importance of selecting countries and settings for pre-introduction studies that are open to innovation and where there is a reasonable likelihood for success.

Marketing approaches: Insights from private-sector and social marketing

A number of lessons from private-sector and social marketing were presented at the meeting to inform microbicide introduction strategies.

In the private sector, marketing is a key consideration in the early stage of product development; in many cases marketing is a driving force behind product development through defining product features. Microbicide development has been influenced by social science and behavioral research among diverse groups of potential users to explore key product attributes and use dynamics. While some of these findings have been incorporated into product development, technical considerations have limited the extent to which this has been possible in first-generation gel-based products. More recent developments in the microbicide field—for example, progress on a vaginal ring and longer-acting topical formulations—are in part responding to expressed user preferences. The field should continue to conduct market and acceptability research among diverse groups and use findings to inform product development

and to guide investment decisions that will determine which products should advance through the pipeline.

As the field moves from product development to product introduction and use, other lessons from marketing will apply. Patterns of use of new technologies can be generalized based on theories of diffusion and innovation. Typically, a number of factors influence the rate at which a new product is adopted: how much behavior change is required, product cost, and investment in marketing.

A number of other key considerations from the marketing field are applicable to microbicide introduction:

- ***Defining market size and market potential***: Various approaches and modeling exercises are used to estimate market size for health care products. When assessing potential markets, forecasters examine past and present practices of current users of similar products, identify the key determinants of product use, and determine what predictions can be made about the future. Because microbicides are a new product category, such analyses are more complicated.
- ***Market segment prioritization***: Prioritization of different market segments is key for growth of a specific product as well as for the overall product category. Prioritization allows for clearer focus on specific user groups, leading to more effective communication strategies. There is a great deal of diversity even within "market segments," which needs to be considered in product positioning and service delivery approaches. For example, an effort to reach "young women" would need to address the heterogeneity of this potential user group: some young women live beyond protective structures of family and school; some are under pressure to exchange sex for gifts, money, or shelter; many are married, while others are unmarried but sexually active. To reach this diverse group will require careful product positioning, as well as identifying and/or creating new social and health delivery platforms.
- ***Product positioning***: Typically, a product is positioned on the basis of one key characteristic, generally its primary benefit. Microbicides could be positioned in terms of disease prevention, promoting sexual health, or enhancing sexual pleasure. Determining how to position a microbicide will depend on the product profile, including its regulatory status, and on the primary market or user group being targeted. For example, a product might be positioned differently for married women than for unmarried adolescents. Decisions on product positioning are critical for the first product of its kind to come to market and in determining the possibilities for positioning any subsequent products.
- ***Product life cycle planning***: It is important to plan the product pipeline. Efforts to introduce a new product need to anticipate what effect the first generation will have on subsequent products in the same category. There are clear advantages and disadvantages of a product being first to market. The first product can capitalize on being new and innovative, and can potentially build a loyal base among initial users. It can also pave the way by introducing and popularizing a concept and by addressing difficult issues. For example, as Norplant was being introduced, a second-generation product was already coming on line; some countries opted to wait for this second-generation product, which was expected to be less

expensive and easier to deliver. Major considerations for planning and anticipating the impact of later-generation products are how quickly they are likely to reach the market and the extent to which users will substitute a new product for the current one.

- ***Market development and market seeding***: Market development involves preparing the market to accept a new product. Some approaches include increasing health-seeking behavior and legitimizing the health condition that a new product will address. For example, a number of pharmaceutical companies have done extensive direct-to-consumer marketing to destigmatize depression in order to increase sales of anti-depressants. Market seeding or pre-launch activities include conducting observational studies, educating health care professionals, forming partnerships with advocacy organizations, and conducting public awareness campaigns.

In the microbicides field a number of the aforementioned activities are underway, and others are being planned. It would be useful to review and consolidate some of these efforts and to identify key areas where additional work would be productive. In some cases, it may be more appropriate to reconceptualize "advocacy" activities as "market development" and to consider allocating funds for these efforts as an essential product development cost.

Additional research and next steps

A number of potential next steps and priority actions can be initiated now, including:

- Establish an interagency microbicides introduction working group to plan, coordinate, and implement relevant activities.
- Develop a prototype pre-introduction protocol for adaptation to different settings.
- Convene a follow-on consultation on current HIV prevention programs and implications for microbicide introduction.
- Develop a protocol for the design, implementation, and evaluation of an "expanded choice" intervention, which would include male and female condoms and microbicides.
- Convene advertising/marketing experts to brainstorm marketing strategies for the microbicide product category.
- Identify feasible and acceptable access strategies for adolescent girls in key countries.
- Consolidate and expand key "market seeding" (pre-launch) activities such as:
  - Initiatives to stimulate health-seeking behavior, particularly among adolescents
  - Educational events, technology updates, and outreach to health care professionals
  - Development of "champions" in key countries
- Plan and initiate research on key issues for microbicides and other new prevention technologies—for example:
  - What evidence is needed in key countries to inform national decisions regarding adoption of microbicides and how they fit into national programs, health systems, and the overall mix of HIV prevention technologies and programs?
  - How do women and girls assess their risk of HIV? How does this self-assessment correspond to actual risk? What practical strategies do women and girls adopt to protect themselves?

What are the implications of these relationships for microbicides?

- How can diverse populations of adolescent girls be effectively and reliably reached with information and products? What kinds of social and/or health delivery platforms currently exist, and how can they be prepared to adequately deliver microbicides and other HIV-prevention products? Where none exist, what is the best way to establish them?
- How can issues of efficacy and a hierarchy of different methods best be explained to potential users? What information, counseling, and support strategies will be needed to ensure safe and effective use?
- What combination of service delivery approaches and mechanisms will be most appropriate for an initial microbicide product? What targeted areas for health systems strengthening are needed?
- What would a "prevention package" look like in terms of products, messages, and delivery, and how could introduction efforts be designed to embrace the concept of an expanded choice hierarchy?

As research on microbicides advances, it is important to continue to draw on experience from other products when considering how best to make proven microbicides available to women. Participants from many sectors—such as the pharmaceutical industry, advocacy groups, policymakers, and public health officials—will bring different perspectives and objectives to this endeavor. The collective insights, experience, and commitment of these groups will be required to meet the challenge of providing women with the tools to protect themselves.

Suggested websites for further information

Alliance for Microbicide Development (AMD)	www.microbicide.org
Contraceptive Research and Development Program (CONRAD)	www.conrad.org
Family Health International (FHI)	www.fhi.org/en/index.htm
Global Campaign for Microbicides	www.global-campaign.org
HIV Prevention Trials Network (HPTN)	www.hptn.org
International Partnership for Microbicides (IPM)	www.ipm-microbicides.org
Microbicides Development Programme (MDP)	www.mdp.mrc.ac.uk
Microbicide Trials Network (MTN)	www.mtnstophiv.org
National Institutes of Health (NIH)	www.nih.gov
Population Council	www.popcouncil.org
US Agency for International Development (USAID)	www.usaid.gov
World Health Organization	www.who.int/en

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PRESENTATIONS

9:00 - 9:20 ***Welcome***

Peter Donaldson, Population Council

9:20 - 9:45 ***Building the Platform for Women's HIV Prevention***

Martha Brady, Population Council

This session will introduce the agenda and objectives for the day. The speaker will then provide an overview of girls' and women's protection strategies, how microbicides fit within an overall approach to HIV risk management, and key issues for microbicide introduction.

9:45 - 10:05 ***Update on the Microbicides Pipeline***

An overview of the microbicide product development pipeline highlighting the different mechanisms of action being explored, as well as the stage of development and general characteristics of products in clinical trials.

Speaker: **Polly Harrison, Alliance for Microbicide Development**
Facilitator: **Lee Claypool, USAID**

10:05 - 10:45 ***Emergency Contraception: Use Dynamics and Messaging***

This session will address the issues associated with a user-dependent, coitally related product where use is strongly correlated with quality of information. The presentation will include a discussion of how the message, messenger, provider, and service type influence use. The speaker will highlight the challenges of taking a product over the counter, re-supply, and scaling up, and the strategic considerations and implications of advance provision versus post-exposure.

Speaker: **Elizabeth Westley, International Consortium on EC**
Facilitator: **Ian Askew, Population Council**

10:45 - 11:00 Break

11:00 - 11:40 ***Challenges and Opportunities of the Female Condom***

This session will review lessons from the female condom: the only female-initiated HIV prevention product currently available. The speaker will describe public-sector and social marketing approaches, highlighting different strategies to positioning and providing the female condom (FC). He will describe how the FC delivery platform may be useful for microbicides.

Speaker: **Mitchell Warren, AIDS Vaccine Advocacy Coalition**
Facilitator: **Naomi Rutenberg, Population Council**

11:40 - 12:20 ***Introducing a Package of Products: CycleBeads, Condoms, and EC***

The speaker will discuss the rationale, development, and evolution of a "package of interventions" to achieve a single reproductive health goal. The presentation will examine how complex messages are communicated, approaches to counseling, and how this package moved from clinical study to public health programs and use.

Speaker: **Victoria Jennings, Georgetown University**
Facilitator: **Elizabeth McGrory, Consultant**

12:20 - 1:00	Break
1:00-1:45	**Lunch Speaker**

Commercialization of Products for "Taboo" Health Areas: An Industry Perspective

Barbara Feringa, Marketing Consultant
This session will briefly explore the strategies used by the private sector in marketing products that address "taboo" health issues. Topics to be discussed include identifying market size and market potential, market segmentation, product positioning, life cycle management, and product adoption. The incorporation of market development strategies to achieve sustainable growth will be discussed, as will its implications for product launches and line extensions.

Facilitator: Martha Brady, Population Council

1:45-2:25 ***Social Marketing of Health Products that Require New Behavior: A Look at Bednets and Point-of-Use Water Treatment***

The presentation will examine how social marketing approaches are used to initiate new behaviors for disease prevention. The speaker will describe the experience with bednets for malaria prevention, and point-of-use water treatment for prevention of diarrheal disease.

Speaker: Brad Lucas, Population Services International
Facilitator: Saul Walker, International Partnership for Microbicides

2:25–3:05 ***A Process of Innovation: History of Contraceptive Implants (Norplant®)***

This session will review the process of introducing a first-generation, new contraceptive product within the context of the family planning paradigm. The speaker will highlight the "pre-introduction" phase developed to bridge clinical trials and introduction, and how Norplant served as a catalyst for quality of care and the strategic approach to contraception introduction. He will also highlight some of the political minefields the effort faced, and the challenges of being first to market.

Speaker: Juan Díaz, Population Council
Facilitator: Sarah Harbison, USAID

3:05 – 3:15	Break
3:15-3:45	***Emerging Tools in HIV Prevention: Male Circumcision***

This session will review the newest approach to HIV prevention through recent clinical trial results, and discuss how the HIV-prevention field is approaching translating these findings from research to practice. The speaker will touch on the implications for population-level risk reduction versus individual risk reduction, behavioral disinhibition, and how these issues are being considered at the policy, program, and user levels.

Speaker: Johannes van Dam, Population Council
Facilitator: Kim Dickson, World Health Organization

3:45-4:45 ***Lessons for Microbicides: Facilitated Discussion***

Participants and speakers will be invited to draw on the presentations and discussion to review and identify lessons for microbicides.

Discussant: Jeff Spieler, USAID
Chair: Lori Heise, Global Campaign for Microbicides

4:45 ***Closing Remarks***

Martha Brady, Population Council

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